

Cobra®

Electrosurgical Unit

Boston
Scientific
EP TECHNOLOGIES™

Operator's Manual

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Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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EP TECHNOLOGIES™

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1. System Description

The Cobra® Surgical System (see Figure 1-1) consists of the Model 4810 or 4811 Cobra® Electrosurgical Unit (ESU), the Cobra® Electrosurgical Probe, and accessories. This system coagulates soft tissue and may be used to produce hemostasis by coagulating blood tissue.

ESU and Accessories

The ESU supplies radiofrequency energy in the range of 450-470 kHz. It operates in a temperature controlled, power limited manner, based on operator settings and temperature feedback provided by thermocouples in the Probe. See Section 5 for more information regarding the ESU and its controls, displays, and accessories (Instrument Cable, ESU Remote Cable, and Optional Footswitch).

Electrosurgical Probe

The Probe is a sterile, single use electrosurgical device intended to be used to coagulate soft tissues. The Probe contains independently selectable electrodes on its malleable distal section. Only Boston Scientific Cobra® Electrosurgical Probes may be used with the ESU.

Principles of Operation

The Probe applies unmodulated monopolar RF power to soft tissue through multiple electrodes to cause a therapeutic effect. The monopolar RF current flows through the tissue towards the Disposable Indifferent Pad (DIP) electrode(s). Two thermocouples are located at each of the Probe electrodes. These thermocouples measure the temperature at the electrode. The temperature signals from the electrodes are analyzed, and RF current is distributed to selected electrodes to maintain the ESU operator set temperature.

Note: In this manual the Model 4810/4811 Cobra® Electrosurgical Unit with Accessories is referred to as the 'System', the Model 4810/4811 Electrosurgical Unit is referred to as the 'ESU' and the Cobra Electrosurgical Probe is referred to as the 'Probe'.

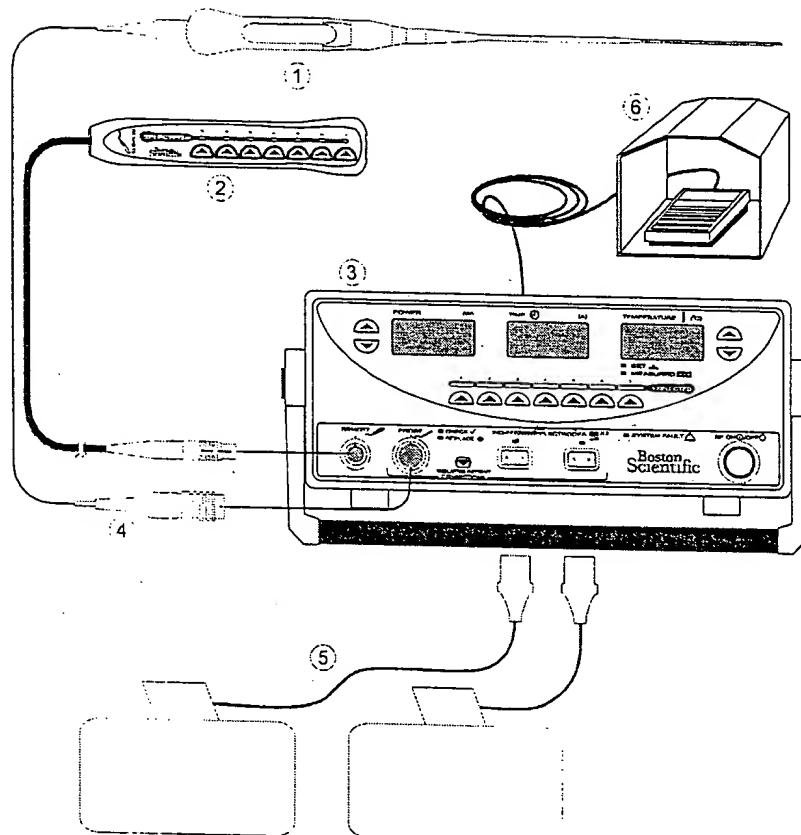


Figure 1-1: System Installation Diagram

Legend

- | | |
|-------------------------|---|
| 1. Electrocautery Probe | 4. Instrument Cable |
| 2. ESU Remote Cable | 5. Disposable Indifferent (Dispersive) Pad (DIP) Electrodes |
| 3. Electrocautery Unit | 6. Footswitch (optional) |

2. Indications/Contraindications

Indications for Use

The System is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The System may also be used to coagulate blood and soft tissues to produce hemostasis.

Contraindications

This system is contraindicated for tissue coagulation in any situation where, in the physician's opinion, excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for coagulation may result.

3. Warnings, Precautions, and Adverse Reactions

Warnings

Before operating the System, read this warning carefully:



Grounding reliability can only be achieved when the power supply cord is connected to a receptacle marked Hospital Only or Hospital Grade.

Precautions

Observe these precautions before using the System:

- Use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues.
- Do not attempt to operate the System before thoroughly reading this Operator's Manual. It is important that the equipment's operating instructions be read, understood and followed. For future reference, retain this Manual in a convenient, readily accessible place.
- The operator should keep the set temperature and power limit as low as possible to achieve the desired end effect. This avoids excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for coagulation.
- Read and follow the Disposable Indifferent (Dispersive) Pad (DIP) Electrode manufacturer's instructions for use. Use only DIP Electrodes which meet or exceed ANSI/AAMI HF-18 requirements.
- Placement of DIP electrodes on thighs can be associated with higher impedances, which can result in automatic RF power shut-off.

- The ESU is capable of delivering significant electrical power. Patient or operator injury can result from improper operation of the System. During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the DIP Electrode or failure of an electrical lead. *Do not increase settings before checking for obvious defects or misapplication.*
- The risk of igniting flammable gases or other materials is inherent in the application of RF power. Precautions must be taken to restrict flammable materials from the surgery site.
- Electromagnetic interference (EMI) produced by the ESU during the delivery of RF power may adversely affect the performance of other equipment.
- DIP Electrodes should be reliably attached with their entire area to the patient's body and as close to the operating field as possible.
- Skin-to-skin contact (for example, between the arms and the body of the patient) should be avoided.
- When the System and physiological monitoring equipment are used simultaneously on the same patient, monitoring electrodes should be placed as far as possible from the Electrosurgical Probe. In any case, monitoring systems incorporating high frequency current limiting devices are recommended.
- The Instrument Cable to the Electrosurgical Probe should be positioned in such a way that contact with the patient or other leads is avoided.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. Refer to the manufacturer's Directions for Use.
- Regularly evaluate and inspect re-usable cables and accessories.
- Boston Scientific relies on the physician to determine, assess and communicate to the individual patient all foreseeable risks of the electrosurgical procedure.

Potential Adverse Reactions

The following adverse events are possible: excessive thermal damage to tissue, or collateral damage to adjacent tissue not intended for coagulation.

4. Unpacking the System

Unpacking

The System's shipping carton and Accessory Kit contain all of the components identified below:

- 1 – ESU
- 1 – Footswitch
- 1 – ESU Remote Cable
- 2 – System Operator's Manuals
- 1 – Instrument Cable
- 6 – Dispersive Indifferent Pad electrodes

To unpack the System, follow these steps:

1. Unpack the ESU and accessories carefully and inspect for damage.
2. Notify the carrier immediately if the shipment carton is damaged.
3. Verify that the items listed above are received.



Call Boston Scientific. If there are any discrepancies, notify Boston Scientific.



Caution: *Do not open unit. Electrical shock hazard.*

Repackaging the ESU

When the ESU requires service or transfer to other location, use the original shipping carton and packing materials to repack and ship the ESU.

For shipping, disconnect the Instrument Cable, ESU Remote Cable, and Footswitch. Place all the components into the locations reserved for these units in the carton.

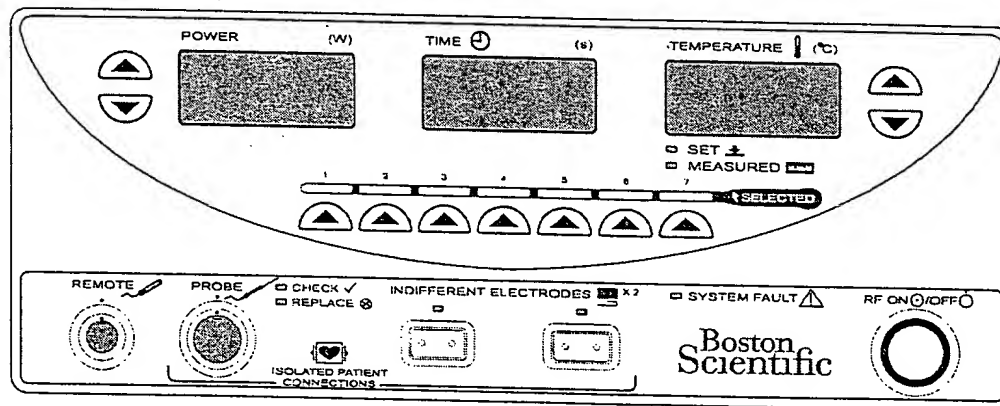
5. Controls, Displays, and Accessories

Front Panel

The operator controls for the System are located on the front panel of the ESU. The buttons on the ESU's front panel allow the user to control the operation of the ESU. The lights/LEDs on the front panel show the ESU's status and/or report error conditions.

This section describes the operator controls on the front panel as shown in Figure 5-1.

Figure 5-1: ESU Front Panel



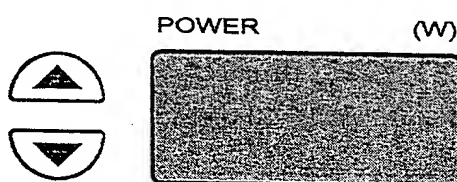
POWER Panel

POWER Display


The POWER Display (see Figure 5-2) shows the RF power output in Watts. When the ESU is initially powered on, the POWER Display indicates the default power limit of 150 W. After the user presses the RF POWER CONTROL Button, the display changes from the power limit value and begins displaying the actual power output the Probe is delivering to the tissue.

During RF delivery, the ESU adjusts power output to maintain an actual measured temperature at the temperature setpoint. Measured power may be lower than setpoint power depending on the measured tissue temperature and/or tissue impedance. When RF power is discontinued, the POWER display reverts to the power limit value.

Figure 5-2: POWER Display and Buttons



POWER Buttons 

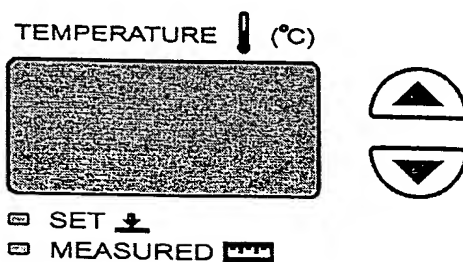
The POWER (increase/decrease) Buttons  select the maximum amount of RF power available for the Deliver mode.

TEMPERATURE Panel


TEMPERATURE Display

The TEMPERATURE Display (see Figure 5-3) shows the temperature setpoint (desired tissue temperature) in degrees Centigrade.

Figure 5-3: TEMPERATURE Display and Buttons



TEMPERATURE Buttons

The TEMPERATURE (increase/decrease) Buttons  select the temperature that the ESU attempts to maintain during RF power delivery. During Deliver Mode, the ESU automatically adjusts power, within the user-selected upper power limit, to achieve the desired tissue setpoint temperature.

SET/MEASURED LEDs

The SET and MEASURED LEDs (see Figure 5-1) indicate the change in value for POWER and TEMPERATURE displays between set values and measured values. Whenever any of the four up/down switches is pressed, the MEASURED LED turns off, the SET LED is lit and both POWER and TEMPERATURE Displays stop indicating measured power and temperature values and display their setpoint values.

RF POWER CONTROL Panel

RF POWER CONTROL Button/Light

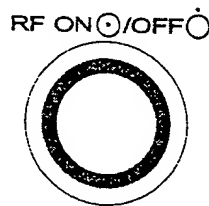
The RF POWER CONTROL Button (see Figure 5-4) controls the two operational modes of the ESU:

- STANDBY mode – This mode allows the setpoint parameters to be adjusted.
- DELIVER mode – This mode is the ESU's state during the delivery of RF power.

When the ESU is initially powered on, the RF POWER CONTROL Light flashes, indicating the ESU is in the STANDBY mode and prepared for RF power delivery. Pressing the yellow RF POWER CONTROL Button once places the ESU into the DELIVER mode and allows the Probe to transfer RF power to the tissue. This button is backlit with a light which is ON during the delivery of RF power (DELIVER mode), and BLINKING when RF power delivery stops (STANDBY mode).

When the user initially presses the RF POWER CONTROL Button, a test of temperature sensor functionality is made prior to delivery of RF power. If a Probe with faulty temperature sensor(s) on more than one electrode is detected by the ESU (which can be caused by short or open in the temperature measurement circuit), the ESU does not enter the DELIVER mode. It enters the STANDBY mode and illuminates the REPLACE PROBE LED, indicating a faulty temperature measuring circuit has been detected. Also, the ELECTRODE SELECTION LED(s) for the electrode(s) with faulty sensor(s) blink.

Figure 5-4: RF POWER CONTROL Panel and Button/Light



Isolated Patient Connector

The ISOLATED PATIENT CONNECTIONS (see Figure 5-1) provide for connection of the Instrument Cable and Electrosurgical Probe to the ESU. The connections have locking mechanisms for secure cable installation. The Instrument Cable and Electrosurgical Probe must be installed in the ISOLATED PATIENT CONNECTIONS before the ESU delivers RF power. These connectors are keyed for proper alignment.

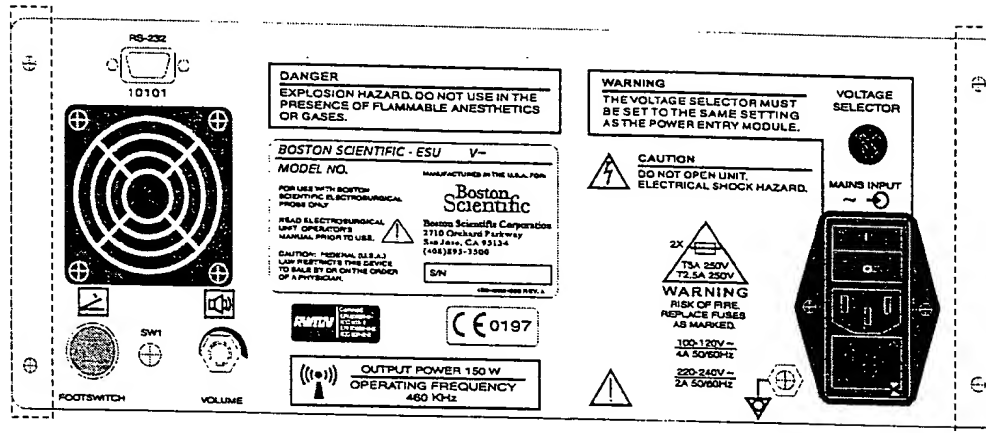
MAINS (Power "ON") Display

The MAINS Display (see Figure 5-1) indicates that the power switch (see Figure 5-5) located on the rear panel is ON ("1" position) and that the ESU is plugged into an electrical outlet.

Rear Panel

This section describes the output ports and power controls on the rear panel shown in Figure 5-5.

Figure 5-5: ESU Rear Panel



POWER Switch

The power switch (rocker switch) on the rear panel powers the ESU ON ("1" position) or OFF ("0" position).

Power Cord

The Power Cord is "Hospital Grade" and must be installed at an AC electrical wall outlet designated "Hospital Grade" or "Hospital Only."

MAINS Fuse Holder

Housing for AC fuse. (See ESU rear panel for appropriate type of fuse.)

Fuse Holders (2)

Housing for AC fuses. (See ESU rear panel for appropriate type of fuse.)

Footswitch Cable Connector

This connector is polarized for connecting the Footswitch Cable.

Volume Control Knob

This knob provides the user with volume control for the audio signal that accompanies RF power delivery. If no audio tone is heard, check the knob to determine if the volume level has been adjusted too low.

Isolated Serial Port

This port is labeled "RS-232." It is provided for use with future optional Boston Scientific approved accessories only.

Ground Stud

Protective Earth Ground stud (chassis ground).

Accessories

Instrument Cable

The Instrument Cable (see Figure 1-1) is inserted into the ISOLATED PATIENT CONNECTION (see Figure 5-1) to connect an Electrosurgical Probe to the ESU. The connector has a locking mechanism for secure cable installation. The Instrument Cable and Electrosurgical Probe must be installed in the ISOLATED PATIENT CONNECTION before the ESU delivers any RF power. This cable uses a circular connector that is keyed for proper alignment.

Footswitch

An optional Footswitch (see Figure 1-1) can alternatively be used to provide ON/OFF control of the RF power delivery. The connecting cable's length allows the user to stand at the operating table near the patient without requiring another person for starting/stopping RF power delivery. The user must continuously hold the Footswitch down for RF power to be delivered. The RF power delivery is immediately terminated when the user's foot is lifted off.

ESU Remote Cable (Remote)

The ESU Remote Cable can also be used for electrode selection when it is connected to the ESU front panel connector labeled "REMOTE" (see Figure 5-1) through a locking 18-pin ESU Remote Connector. The ESU Remote Cable functions similarly to the front panel ELECTRODE

SELECTION Panel; they are both functional when the ESU Remote Cable is connected.

ELECTRODE SELECTION Buttons

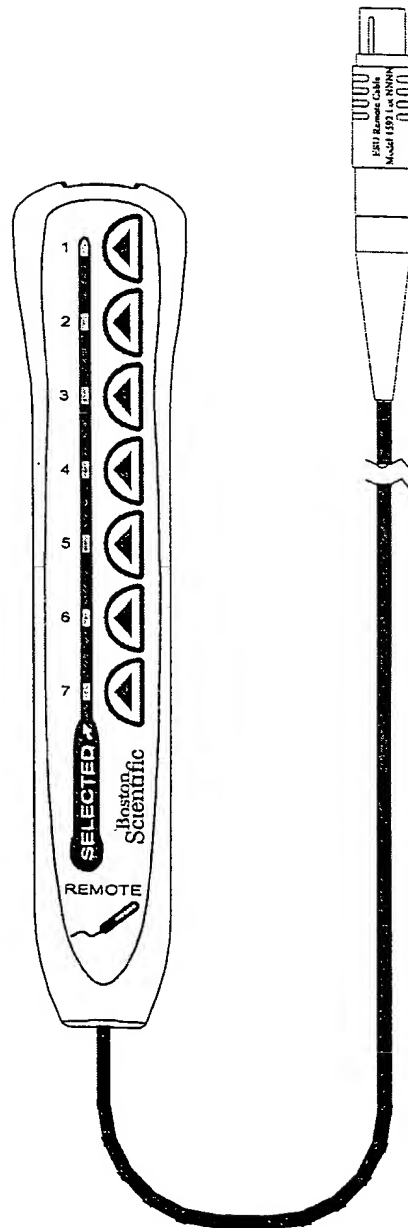
The seven ELECTRODE SELECTION Buttons (see Figure 5-6) located on the ESU Remote Cable may be used to select one to seven electrodes for simultaneous RF delivery. The System is capable of delivering RF power to multiple electrodes simultaneously while maintaining all selected electrodes at a desired set temperature. At least one electrode must be selected to enable RF delivery; otherwise, the ESU remains in STANDBY and emits the Error tone. Depressing an ELECTRODE SELECTED Button either enables or disables that electrode. During delivery of RF power, the ELECTRODE SELECTED Buttons are not operable.

SELECTED ELECTRODE LEDs

Each of the seven SELECTED ELECTRODE LEDs (see Figure 5-6) displays the status of a Probe electrode. If the LED is illuminated, the electrode will deliver RF power. If the LED is NOT illuminated, the electrode is disabled and will not deliver RF power. Electrodes which may be selected depend on the Electrosurgical Probe type. Also, defective Probe electrodes may not be selected. If a Probe electrode is not selectable, the ESU emits the Error tone when the corresponding ELECTRODE SELECTED Button is depressed and the SELECTED ELECTRODE LED will not illuminate. During the DELIVER Mode, the SELECTED ELECTRODE LEDs display those electrode(s) being used to deliver RF power from the ESU, as well as electrode(s) in which problems have been detected.

The ELECTRODE SELECTED Buttons do not operate in the DELIVER Mode; they can only be used in the STANDBY Mode.

Figure 5-6: ESU Remote Cable



6. Operational Sequence

Initial Installation

Follow the instructions in this section carefully to prepare the System for operation:

1. Connect the ESU Power Cord plug into a properly grounded AC electrical outlet designated "Hospital Grade" or "Hospital Only."

Note: Never use an outlet without a grounding connection.

2. Position the ESU for easy viewing of its front panel displays.
3. If using the ESU Remote Cable, install its cable connector to the ESU REMOTE socket on the ESU front panel by carefully lining up the red dot on the connector with the red dot at the top of the socket. Push the connector firmly into the socket until it locks in place.
4. To disconnect the ESU Remote Cable from the ESU, grasp the connector and pull it straight out of the socket.

Note: Do not disconnect the ESU Remote Cable by pulling on the cable.

5. Install two DIP Electrodes into the INDIFFERENT ELECTRODE receptacles located on the ESU front panel (see Figure 5-1) as follows:
 - a. Read the manufacturer's manual before installing the DIP Electrode pads.
 - b. Gently push each DIP Electrode fitting straight and firmly into place.
 - c. To disconnect a DIP Electrode, grasp the DIP Electrode fitting and gently pull it out from the ESU front panel receptacle.

Note: Do not disconnect a DIP Electrode Connector by pulling on its cable.

- d. Before use, check the DIP Electrodes for damage to the sealed foil packages. Exposure to air, due to a damaged package, could cause the DIP Electrodes to become dry and limit their grounding capability.

- e. Be sure the pads are moist and sticky to the touch before placing on the patient.

Note: Do not attempt to relocate the patient grounding pad after initial application. Electrode gel is NOT required and should NOT be used.

- f. Two DIP Electrodes should be placed on a well-vascularized, convex skin surface that is in close proximity to the electrosurgery site. Avoid scar tissue, bony prominence, adipose tissue, or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Avoid wrinkles or folds when applying the pads as wrinkles and folds decrease conductivity.

Note: The ESU limits RF output to 1 A of current flow through either of the DIP Electrode connectors.

- 6. If using the Footswitch, install its cable connector into the FOOT-SWITCH Cable Connector on the ESU rear panel. Carefully push the cable connector into the FOOTSWITCH connector until it is seated firmly in place.

Note: Do not twist or bend the FOOTSWITCH connector during insertion as this action may cause damage to the pins.

- 7. Position the Footswitch to allow easy access by the physician.
- 8. When the Electrosurgical Probe is ready for use, install the Instrument Cable to the ISOLATED PATIENT CONNECTOR socket on the ESU front panel by carefully lining up the spline on the connector with the top of the socket. Push the connector firmly into the socket until it locks in place.
- 9. To disconnect the Instrument Cable from the ESU, grasp the connector and pull it straight out of the socket.

Note: Do not disconnect the Instrument Cable by pulling on the cable.

Turning the ESU "ON"

- 1. Turn the ESU ON by pressing the power switch (to the "1" position) located in the power input module on the ESU rear panel (Figure 5-5).

The ESU automatically initiates a self-test procedure which is indicated by the illuminated front panel and ESU Remote displays and continuous audio tone generated for approximately 2 seconds. If no system malfunction is detected, the ESU proceeds to the STANDBY Mode.

Note: The connection between the Electrosurgical Probe and ESU is not required to complete the initial self-test.

2. If a system malfunction is detected during self-test, all front panel displays remain lit and the ESU does not operate. To clear any malfunctions found during self-test, the ESU must be powered OFF, then back ON. The self-test repeats.



Call Boston Scientific for Service. A second self-test failure is indicative of an ESU malfunction and should be referred to Boston Scientific for service. The ESU does **NOT** operate unless the initial self-test has been successfully completed.

STANDBY Mode

The STANDBY mode is designed for setting the desired parameters for RF power delivery. It is automatically initiated after completion of a successful ESU self-test. STANDBY mode is indicated by a flashing RF POWER CONTROL Button on the ESU front panel; TEMPERATURE, TIME, and POWER Displays are continuously lit. Values displayed when the ESU is first initialized are 70° C in the TEMPERATURE Display, 0 seconds in the TIME Display, and 150 W in the POWER Display. (Refer to Figure 5-1 for the location of displays and buttons.)

ESU in STANDBY Mode

When the ESU is first powered on and has successfully completed its self-test, the TEMPERATURE Display initially indicates 70° C. The user must attach an Electrosurgical Probe and then select the desired Probe electrodes through either the front panel or the Remote before RF power delivery. Electrodes cannot be selected without first attaching an Electrosurgical Probe. Depressing an ELECTRODE SELECTION Button without an Electrosurgical Probe connected causes the ESU to emit the Error tone.

ESU in DELIVER Mode

When the ESU is in the DELIVER Mode, the TEMPERATURE Display indicates "LO" if the measured temperature is less than 15° C, "HI" if temperature is greater than 120° C. Otherwise, it shows the measured temperature (see Figure 5-3).

Selecting the Power Limit

The RF power limit (150 W maximum) is the maximum amount of power that the ESU will deliver to achieve and maintain the desired setpoint tissue temperature. If the RF power limit is equal to or greater than the amount of power necessary to achieve and maintain the desired tissue temperature, then the ESU supplies the appropriate amount of power to achieve the temperature setpoint. The ESU only supplies as much RF power as necessary to achieve the desired tissue temperature.

If the RF power setpoint is less than the amount of power required to achieve and maintain the desired tissue temperature, the ESU will not achieve the desired tissue temperature and thus the measured temperature will be less than the desired tissue temperature.

ESU in STANDBY Mode





When the ESU is first powered on and has successfully completed its self-test, the POWER Display initially indicates 150 W. The user must attach an Electrosurgical Probe and then select the desired Probe electrodes through either the front panel or the Remote before RF power delivery. Electrodes cannot be selected without first attaching an Electrosurgical Probe. Depressing an ELECTRODE SELECTION Button without an Electrosurgical Probe connected causes the ESU to emit the Error tone.

ESU in DELIVER Mode

When the ESU is in the DELIVER Mode, the POWER Display indicates delivered power (see Figure 5-2).

Selecting the RF Power Limit

To change the RF power limit (in Watts), follow these steps:

1. Press the appropriate POWER Button  to increase or decrease the RF power limit by 1 W. The SET LED is illuminated to indicate that the value in the POWER Display is the RF power limit.
2. To scroll rapidly to the desired power setpoint, depress and hold the appropriate POWER Button  down.
3. Release the POWER Button  when the POWER Display shows the appropriate RF power limit. The MEASURED LED is then illuminated to indicate that the value in the POWER Display is the current value of measured power.
4. During RF power delivery (Deliver mode), the power setpoint can be adjusted in 1-W increments to provide better control during the procedure by pressing the appropriate POWER Button . When the button is released, the POWER Display returns to showing the current value of measured power.

Selecting the Desired Tissue Temperature





For tissue coagulation, it is recommended that the operator initially select the lowest possible set temperature (from 55° C to 70° C). It should be noted that measured temperature may be slightly lower than maximum tissue temperature. Measured temperature may be influenced by the degree of tissue contact.

Selecting Temperature

If the Electrosurgical Probe is connected to the ESU, the default value for desired tissue temperature (temperature setpoint) can be changed. The ESU

automatically adjusts power, within a user-selected upper power limit, to achieve the desired tissue temperature.

To change the temperature setpoint for the ESU, follow these steps:

1. Ensure that the ESU is in STANDBY mode.
2. Press the appropriate TEMPERATURE Button  to increase or decrease the temperature setpoint by 1° C. The SET LED is illuminated to indicate that the value in the TEMPERATURE Display is the temperature setpoint.
3. To scroll rapidly to the desired temperature setpoint, depress and hold the appropriate TEMPERATURE Button down.
4. Release the TEMPERATURE Button  when the TEMPERATURE Display shows the appropriate temperature setpoint. The MEASURED LED is then illuminated to indicate that the value in the TEMPERATURE Display is the current value of measured temperature.
5. The tissue temperature selection range is 50° to 100° C in increments of 1° C, although the ESU cannot achieve a temperature which is less than the ambient tissue temperature.
6. During RF power delivery (DELIVER Mode), the temperature setpoint can be increased or decreased by pressing the appropriate TEMPERATURE Button . When the TEMPERATURE Button  is depressed, the SET LED is illuminated, and the display shows the new temperature setpoint. When the button is released, the MEASURED LED is illuminated, and the display shows the present value of tissue temperature.

Adjusting the Audio Control

The user may adjust the volume of the audio signal when the ESU is initially powered on or during a surgical procedure.

1. Adjust the volume of the audio signal by rotating the Volume Control Knob on the ESU rear panel (see Figure 5-5).

2. If desired during a clinical procedure, the Volume Control Knob may be rotated fully counter-clockwise to its lowest setting.

Note: At the minimum setting, the tone may NOT be audible during RF power delivery.

Turning the RF Power Delivery “ON”

To deliver RF power to the Probe, follow these steps:

1. Ensure that all connections are secure and correct.
2. Verify that all preceding selections have been made.
3. To begin RF power delivery, press the RF POWER CONTROL Button once or hold the Footswitch down. The POWER Display shows the RF power delivered to the Probes (in W).

The *Deliver* tone sounds during normal RF power delivery.

When RF power is delivered to the Probe, the displays function as follows:

RF POWER CONTROL BUTTON/Light

This light illuminates and remains lit until RF power delivery is discontinued. (For instructions on how to discontinue RF power delivery, see the section, *Turning the RF Power Delivery “OFF”* on page 6-8).

POWER Display

This display shows (in W) RF power delivered to the Probe. The value may fluctuate slightly due to changes in tissue contact.

TEMPERATURE Display

This display shows (in °C) the maximum temperature measured by any selected Probe electrode. The value may be slightly lower than the actual maximum tissue temperature.

TIME Display

This display shows the elapsed time as follows:

When the RF POWER CONTROL Button is pressed or the Footswitch is depressed, this display starts from 0 seconds and begins to count up.

When loss of contact with tissue is detected at all Probe electrodes, the TIME Display stops for up to 10 seconds. If contact with tissue is not restored within 10 seconds, the ESU returns to STANDBY, emits the Error tone and RF delivery ceases.

Directions for Use

Once the Electrosurgical Probe has been positioned, RF power is delivered via the ESU resulting in the coagulation of the targeted tissue. Temperature can be monitored during the coagulation procedure through the sensors embedded within Probe electrodes.

1. Follow steps given in the sections, *Initial Installation* on page 6-1, and *Turning the ESU "ON"* on page 6-2.
2. Follow steps given in the *Directions for Use of the Electrosurgical Probe*.
3. Connect the Probe to the ESU by plugging in the Instrument Cable.
4. Select the desired Probe electrodes with the ELECTRODE SELECTED Buttons on either the front panel or the ESU Remote Cable.
5. When the coagulation site has been accessed and the selected Probe Electrodes are in contact against the tissue surface, RF power may be delivered as described in section, *Turning the RF Power Delivery "ON"* on page 6-7. RF power is delivered in a monopolar mode to the tissue via the selected probe electrodes and the DIP electrodes on the patient's skin, resulting in coagulation under the selected Probe electrodes. Temperature sensors in the electrodes allow temperature control of RF delivery, resulting in more consistent coagulation without over temperature effects.

Turning the RF Power Delivery "OFF"

RF power delivery ceases by user intervention or certain operating conditions listing in the next section, *Possible Causes of RF Power Delivery Interruption*.

To discontinue RF power delivery during operation (DELIVER Mode), the user may either:

- Press the RF POWER CONTROL Button or
- Release the Footswitch.

Possible Causes of RF Power Delivery Interruption

RF power delivery can cease due to operating conditions other than user intervention. RF power automatically ceases when:

- The ESU detects a current of 1.1 A or more in either of the two DIP Electrode connectors.
- Impedance is less than $25\ \Omega$.
- Impedance is greater than $300\ \Omega$ for more than 10 seconds.
- Temperature of a non-selected electrode exceeds 50°C for more than 3 seconds.
- The ESU detects a current of 0.9 A or more in any Probe electrode for more than 3 seconds.
- Temperature of an electrode exceeds 120°C for more than 1 second.
- Temperature of the hottest electrode exceeds the temperature of the coolest electrode by more than 15°C for more than 5 seconds.
- System operation errors are detected.

Correcting a CHECK PROBE Condition

If the CHECK PROBE LED is lit during RF power delivery, follow these steps:

1. Ensure that the connection between the Probe and ESU is correct and secure.
2. Ensure that the connection between each DIP Electrode and the ESU is correct and secure.

3. Ensure that each DIP Electrode is properly applied.
4. If an improper cable connection is not the cause of the CHECK PROBE condition, then a build-up of coagulum on the Probe electrodes may be the cause, and RF power output should be discontinued.
5. To discontinue RF power delivery, refer to the instructions in section, *Turning the RF Power Delivery "OFF"* on page 6-8.

Correcting a REPLACE PROBE Condition

If the REPLACE PROBE LED is lit, follow these steps:

1. Ensure that the connection between the Probe and the ESU is correct and secure.
2. Replace the Probe if the REPLACE PROBE condition persists.
3. Replace the Instrument Cable if replacing the Probe does not correct the REPLACE PROBE condition.

7. Service and Maintenance

The ESU requires no routine service or maintenance. If the ESU fails to operate when plugged into a proper AC power receptacle and the power switch is turned on, check the fuse (refer to Replacing the Fuses in this chapter).

The ESU contains no user-serviceable parts; disassembly and attempted repair by unqualified personnel may create a hazardous condition and voids the warranty.



Call Boston Scientific for Service. If a second failure occurs, notify Boston Scientific for service.



Caution: *Do not open unit. Electrical shock hazard.*

Cleaning/Disinfecting

The outer surfaces of the ESU and its accessories may be cleaned with a mild soapy solution. If disinfection is required, isopropyl alcohol may be used to clean the outer surfaces.

Note: Do not immerse the ESU or its accessories in any liquid. Avoid caustic or abrasive cleaners.

The Instrument Cable and ESU Remote Cable may be re-sterilized up to 20 times with Ethylene Oxide (EO) only. The ESU is not to be sterilized. The Electrosurgical Probe is single-use only and must not be re-sterilized. The following methods are recommended for their ability to clean, disinfect and sterilize ESU cables. It is the user's responsibility to qualify any deviations from these processing methods.

Prior to cleaning the re-usable ESU cables, visually examine each cable and its connectors.

1. If liquid has entered the end cavities of a connector, the cable cannot be reliably cleaned or re-sterilized and should be replaced.
2. Visible contamination on any connector contacts may result in increased frequency of ESU errors; such cables should be replaced.
3. For easier cleaning, cables contaminated with blood or other body fluids should be cleaned before the contamination can dry.

Cleaning

1. Protect connectors and electrical contacts during cleaning processes. Exposure to water or cleaning agents will damage the contacts; such cables should be replaced.
2. Prepare an enzymatic pre-soak (e.g. Klenzyme™) according to manufacturer's recommendations.
3. While suspending connectors, allow cables to soak a minimum of 2 minutes (for Klenzyme™ solution) or as recommended by manufacturer. Do not immerse connectors.
4. While protecting connectors, rinse cable thoroughly in warm, running tap water.
5. Prepare a detergent cleaning agent (e.g. Manu-Klenz™) according to manufacturer's recommendations.
6. Use a soft-bristle brush to manually clean the cable while immersed in the detergent. Do not immerse the connectors.
7. While protecting the connectors, rinse the cables thoroughly, by holding under a steady stream of warm tap water (30-35° C) for approximately 3 minutes.
8. Dry the devices with a gauze pad taking special care to dry the end cavities of the connectors.
9. Conduct a final confirmation of the cleaning process by visually inspecting the cable for remaining soil.

Disinfection

Disinfection is recommended in 2.4% Glutaraldehyde solution (e.g. Cidex Plus™).

1. Prepare Cidex Plus™ disinfectant solution according to manufacturer's recommendations. Verify the efficacy of the Cidex Plus™ by using the Cidex Plus™ Solution Test Strip to determine that at least the "minimum effective concentration" (MEC) of glutaraldehyde is present and pH is within recommended range.

2. While suspending connectors, allow cables to soak in a container of Cidex Plus™ solution at a room temperature (20-25° C) for a minimum of 10 minutes. Do not immerse connectors.
3. While protecting the connectors, rinse the cables thoroughly in warm tap water (30-35° C) for approximately 3 minutes.
4. Dry the devices with a gauze pad taking special care to dry the end cavities of the connectors.

Sterilization

Place dry unit in breathable Tyvek pouch.

Apply biological indicator according to validated hospital procedure.

Place in sterilization chamber. Follow hospital's recommended EO exposure cycle with biological indicators, or use the following validated cycle:

1. Preconditioning (Dwell)
 - Temperature: 125-145° F (52-63° C)
 - Humidity: 55-75%
 - Vacuum 1.9-3.9 psia (13.1-26.9 kPa)
 - Time: 30-45 minutes
2. Exposure
 - Sterilant gas: 100% EO
 - Gas Concentration: 600 ± 50 mg/L
 - Temperature: 125-145° F (52-63° C)
 - Full cycle exposure time: 4 hours.
3. Post Vacuum
 - 1.9 - 3.9 psia, (13.1-26.9 kPa) 2 times
4. Aeration
 - 12 hours mechanically at 120-145° F (49-63° C)

Reuse Life

ESU cables are expected to perform within electrical specifications after 20 exposures to a typical hospital EO cycle. The actual reuse life of a device will vary depending on its use and handling.

The ESU detects open circuits and short circuits in the cables and prevents use of the system until they are replaced. Prior to use it is recommended that connector contacts of the cables again be visibly inspected for contamination and corrosion. Corrosion on the cables will cause inaccurate readings; such cables should be replaced.

Replacing the Fuses

Replacing the Main Fuse

1. Before replacing a fuse in the ESU, disconnect the mains power cord from the ESU.
2. Replace the fuse with another of the same type and rating. Refer to the fuse label on the rear panel (see Figure 5-5).
3. Pull the fuse holder out of the power entry module.
4. Use a slotted screwdriver to assist in removing the fuse holder.
5. Insert the new fuse in the fuse holder and reinsert it in the power input module.

Note: When replacing the fuse holder, ensure the fuse holder is inserted in the correct orientation for the operational voltage level.

8. Product Specifications

General Specifications

Table 8-1 lists the specifications for the System (ESU and Accessories).

Table 8-1: System Specifications

Description	Specification
Power Specifications	
Line Power	100 – 120 V~ (Model 4810) 220 – 240 V~ (Model 4811)
Current Rating	5 A, 50/60 Hz (100 – 120 V~)
Fuse Rating	2,5 A, 50/60 Hz (220 – 240 V~)
Power Cord Length	10 ft. (3 m)
Footswitch	
Cable Length	10 ft. (3 m), Connector (to ESU): Polarized
Moisture Protection Rating	IPX8
Instrument Cable	
Length	10 ft. (3 m)
Connector	30-pin Polarized Quick-Connect Connector
ESU Remote Cable	
Length	10 ft. (3 m)
Connector	18-pin Polarized Quick-Connect Connector

Table 8-1: System Specifications

Description	Specification
Indifferent Electrode Current Limit	RF output to the patient is limited if more than 1 A (+20%, -0%) flows in either INDIFFERENT ELECTRODE.
ESU RF Power Outputs	<ul style="list-style-type: none"> RF energy is delivered at 460 kHz, as a sinusoid. 150 W maximum into a minimum impedance of 37.5 Ω, with a 2 A_{RMS} current limit. (See Figure 8-5.) Maximum output voltage is 178.5 V_{RMS}. Maximum RF power output is based on Probe type.
Impedance	<ul style="list-style-type: none"> Measures 25 Ω and above, if accessing up to 150 W of RF power. Measures up to 999 Ω.
Temperature Normal Operating Condition: With ESU in the DELIVER Mode Outside of Normal Operating Range	<p>Allows selection of desired tissue temperature (temperature setpoint) within the range of 15° to 120° C.</p> <p>ESU measures 15° to 120° C. ESU displays "LO" or "HI".</p>
Power Limit	Allows selection of power limit within the range of 1 W – 150 W.

Table 8-1: System Specifications

Description	Specification
Time Measurement	0 to 600 seconds in increments of 1 second.
Shutdown Limits Measured Temperature Measured Impedance	Below 0° C or above 120° C. Below 25 Ω or above 300 Ω for more than 10 seconds.
Measurement Accuracy Power Impedance Temperature	$\pm 5\%$, ± 2 W (see Figure 8-2) $\pm 5\%$, ± 5 Ω (see Figure 8-3) $\pm 3\%$, $\pm 2^\circ$ C (see Figure 8-4)
Dimensions Height Width Depth Weight	6 in. (15 cm) 14 in. (36 cm) 14 in. (36 cm) 22 lb. (10 kg)
Low-Frequency Leakage (50/60 Hz); Source Current, Patient Leads, All Outputs Tied Together Normal Polarity, Intact Chassis Ground Normal Polarity, Ground Open Reverse Polarity, Ground Open Sink Current, at 120 V Applied, All Inputs Chassis Source Current, Ground Open	 <10 μ A <50 μ A <50 μ A <50 μ A <500 μ A

Environmental Specifications

Table 8-2 lists the environmental specifications for the System.

Table 8-2: Environmental Specifications

Description	Specification
Storage	
Temperature	–40° C to 70° C The unit should be gradually returned to the operating temperature range before use and stabilized for one hour before operation.
Relative Humidity	10% to 100%, non-condensing The unit should be gradually returned to the operating environmental conditions before use and stabilized for one hour before operation.
Operation	
Temperature	10° C to 40° C
Relative humidity	30% to 75%, non condensing

Error Codes

Table 8-3 defines the fault LED's for the ESU.

Table 8-3: Error Codes

LED	Description
"Replace"	Temperature not measured (bad thermocouples)
"Replace"	Invalid Probe ID
"Check"	Temperature of non-selected electrode > 50° C
"Check"	Current > 0.9 A for 3 seconds for any probe electrode
"Check"	Impedance > 300 Ω for more than 10 seconds
"Check"	Hottest electrode > 15° C hotter than coolest electrode for > 5 seconds
"Indifferent Electrode"	Current through an indifferent electrode > 1.1 A for > 1 second
"System Fault"	Calibration error
"System Fault"	Software or hardware error
"System Fault"	Apparent power < real power
"System Fault"	Apparent power measured > setpoint
"System Fault"	Voltage, power, or current limit exceeded
"System Fault"	Temperature > 120° C or < 0° C for > 1 second
"System Fault"	System operation error

"System Fault" LED

If the "System Fault" LED is illuminated, turn the ESU "OFF." Wait approximately 4 seconds before turning the ESU "ON."



Call Boston Scientific for Service. If the ESU does not successfully pass the self-test procedure, or if the "System Fault" LED occurs again following successful completion of the self-test procedure, notify Boston Scientific for service.

Figure 8-1: Labeling Symbols



























Increase/Decrease 	Time 	Temperature 	Select 
Set 	Measured 	Selected 	Remote Cable 
Probe/Instrument Cable 	Check 	Replace 	Defibrillator-Proof Type Equipment 
Disposable Indifferent Pad Electrode 	Attention, Consult Accompanying Documents 	RF ON 	RF OFF 
Serial Data 	Dangerous Voltage 	Mains Input 	Footswitch 
Loudspeaker Volume 	Non-ionizing Radiation 	Fuse 	Equipotentiality 
	Power ON 	Power OFF 	

Figure 8-2: Power measurement accuracy graph
 Region between the lines indicates possible error range.

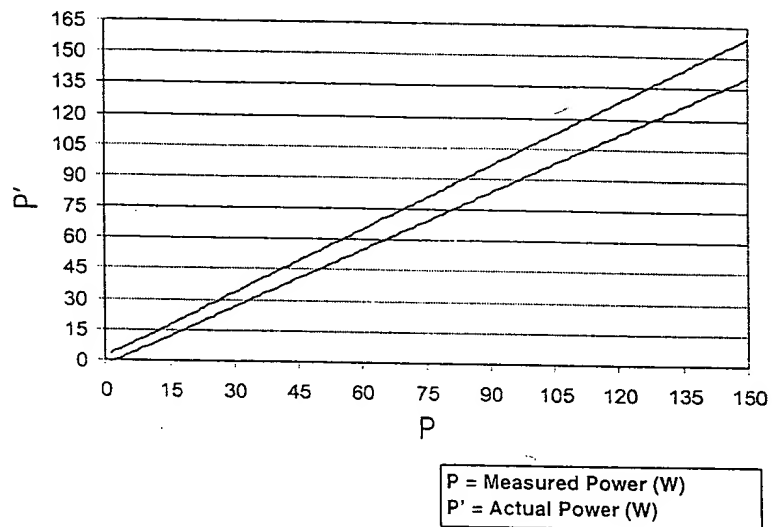


Figure 8-3: Impedance measurement graph
 Region between the lines indicates possible error range.

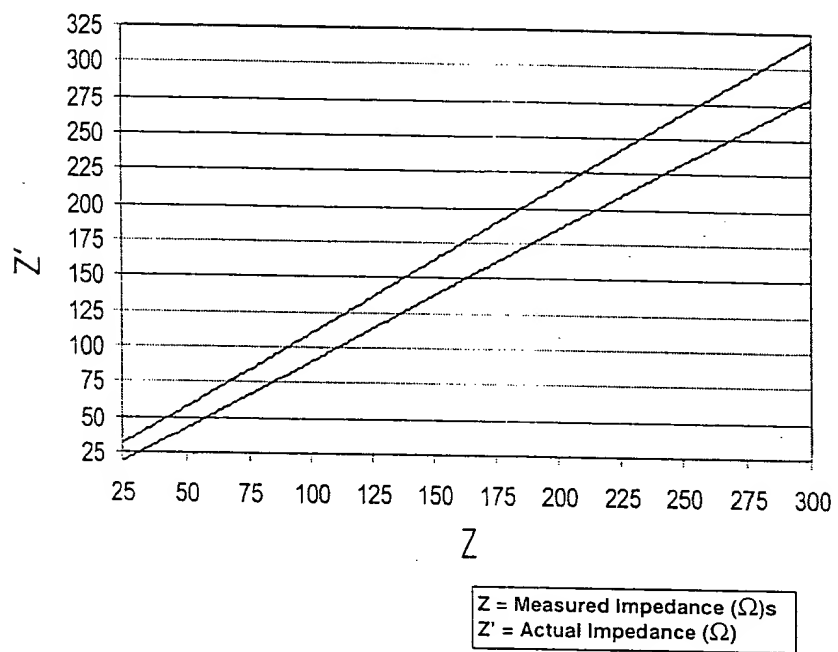


Figure 8-4: Temperature measurement graph
Region between the lines indicates possible error range.

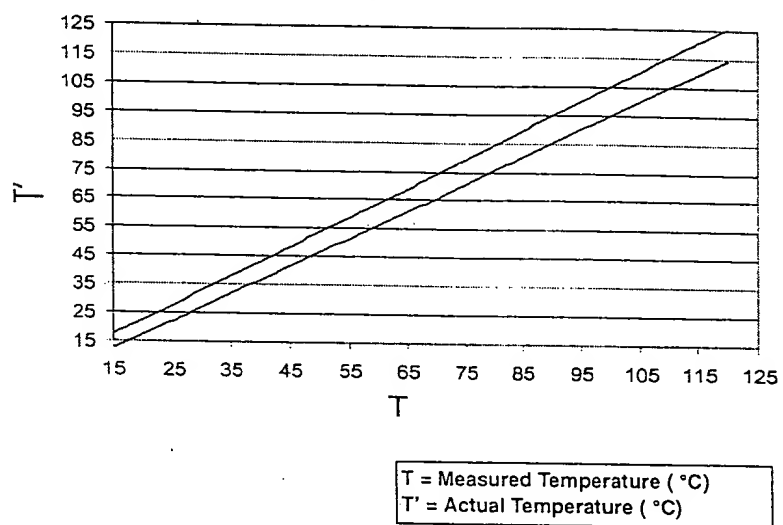
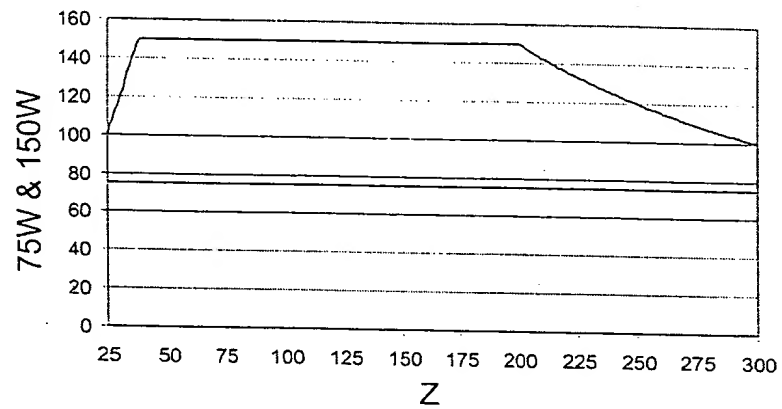


Figure 8-5: Power Output versus load at full and half power
 Curves start at 25 Ω , the minimum impedance required to output RF energy.
 Curves end at 300 Ω , the maximum impedance allowed to continuously output RF energy.



Vertical axis = output at full and half power (W)
 Horizontal axis = load impedance (Ω)

9. Limited Warranty and Disclaimer

Limited Warranties

Boston Scientific warrants that this product is free from defects in original workmanship and materials. If this product is proved to be defective in original workmanship or original materials, Boston Scientific, in its absolute and sole discretion, will replace or repair it, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products which have been used for their normal and intended uses. Boston Scientific's limited warranty shall NOT apply to Boston Scientific products which were installed or calibrated by persons not authorized by Boston Scientific or which have been repaired, altered, or modified in any way and shall NOT apply to Boston Scientific products which have been improperly stored or improperly installed, operated or maintained contrary to Boston Scientific's instructions.

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There are no warranties of any kind which extend beyond the description of the warranties above. Boston Scientific disclaims and excludes all warranties, whether expressed or implied, of merchantability of fitness for a particular use or purpose.

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In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Boston Scientific shall not be liable for damages for loss of profits or revenues, loss of use of the product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damages. Boston Scientific's sole liability

for damages shall be limited to the cost to buyer of the specified goods sold by Boston Scientific to buyer which give rise to the claim for liability.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

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U.S. patents pending; foreign counterparts also pending